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10/505,171	08/31/2004	Kanako Suzuki	80179(302730)	5261
21874 7590 03/17/2010 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER HIBBERT, CATHERINE S				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,171

Applicant(s)

SUZUKI ET AL.

Examiner

CATHERINE S. HIBBERT

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8, 9, 11, 12 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-9, 11-12 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants Amendment to the Specification and Drawings filed 1 October 2009 is received and entered. Applicant's Amendments to the Claims filed 3 September 2008 are received and entered. Claims 4-7, 10 and 13-14 are cancelled. Claims 1-3, 8-9, 11-12 and 15-19 are pending and under examination in this action.

Response to Amendments/Arguments

All rejections to cancelled claim 7 are moot.

Any/all rejections not repeated are withdrawn herein.

Claim Rejections - 35 USC § 102-maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-9 and 15-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Minetoki et al in "Improvement of promoter activity by the introduction of multiple copies of the conserved region III sequence, involved in the efficient expression of *Aspergillus oryzae* amylase-encoding genes" (Appl Microbiol Biotechnol, 1998:50 p.459-467, of record) for reasons of record and below. The rejection of cancelled claim 7 is moot.

The applicants response is to traverse the rejection under 102(b), as anticipated by Minetoki et al stating that the Minetoki et al reference does not teach or suggest all the limitations of the instant claims. The applicants submit:

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Claim 1 recites a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter, wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter, and wherein the modified promoter is capable of functioning in a filamentous fungus.

To anticipate a claim, each and every element of the claim must be found in a single reference.

This is discussed in the Manual of Patent Examining Procedure § 2131:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the..., claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The applicants traverse that the Minetoki et al. reference does not teach or suggest all the limitations of the instant claims. In particular, Applicants state that

nowhere does the Minetoki reference expressly or inherently teach or suggest a modified promoter capable of functioning in a filamentous fungus according to the instant claims, where a first DNA fragment and a second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, and where said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter region.

Furthermore, Applicants point to Figure 2 of Minetoki et al "which schematically depicts the promoter as taught by the Minetoki reference" and argue that "nowhere does Minetoki teach an existing CCAAT sequence and an existing SRE as set forth in the instant claims". Applicants

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then compare Figure 2 of Minetoki et al to Figure 4 of the instant Application, “which shows a schematic of insertion positions of a CAAT sequence of SRE in exemplary modified promoters of the invention”. Specifically, Applicants submit that “In Figure 4, the wild type promoter (shown on top, TaaP), has both the CCAAT sequence and SRE, while the bottom construct, as instantly claimed, contains the originally existing CCAAT and SRE and a CCAAT sequence and SRE inserted at the same time (inserted fragment show in box)”. Therefore, Applicants argue that “when comparing Figure 2 (of Minetoki) and Figure 4 of the instant Application, it is clear that the promoter as taught by the Minetoki et al. reference and the promoter as instantly claimed are different”.

In addition, Applicants point to Figures 1 and 2 of the Minetoki reference, stating: It is apparent from Figures 1 and 2 that IIIa (including a sequence corresponding to the second DNA fragment) located at 5'-end side and IIIB (including a sequence corresponding to the first DNA fragment) located at 3'-end side, are paired. Thus, the arrangement of elements in the promoter region as taught by the instant invention is not taught by the Minetoki reference. As pointed out by the Examiner, in the constructs depicted in Figure 2 of Minetoki et al., IIIB and IIIa are arranged, in part, sequentially from the 5'-end side to the 3'-end side. However, IIIB at the 5'-end side and IIIa at the 3'-end are not paired. If, as the Examiner asserts, IIIB at the 5'-end side and IIIa at the 3'-end are paired, unpaired IIa and IIIB remain, which is not possible according to the Examiner's interpretation of the reference.

Therefore, Applicants conclude that “the Minetoki reference does not teach or suggest a modified promoter where a first DNA fragment and a second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter region and accordingly, that “the Minetoki reference does not teach the limitations of the instant claims”.

The applicant's arguments (Remarks filed 3 September 2008) have been fully considered but are unpersuasive for reasons of record and below.

The instant claims are directed to a product and not to the process by which the product was made. The MPEP [2113 [R-1]] states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps". The MPEP states that

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Amended Claim 1 is directed to a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter wherein one first DNA fragment and one second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, and wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter region. and wherein the modified promoter is capable of functioning in a filamentous fungus. In addition, it is noted that the sequence "CGGAAATTTAAAGG" also reads on a full-length SRE sequence (described above) which meets the limitations of the newly amended Claims 1 and 11.

Minetoki et al teach wherein a plurality of said first DNA fragments and a plurality of said second DNA fragments are inserted (claim 8), and further to wherein the same number of said first DNA fragments and said second DNA fragments are inserted (claim 9). For example, Minetoki et al teach modification of the promoter for the *Aspergillus oryzae* amyB gene (see title and abstract). Furthermore, Minetoki et al teach inserting multiple copies of Region IIIa sequence which contains the second base sequence "CGGAAATTTAAAGG" inserted in tandem with the Region IIIb sequence which contains the first DNA fragment including the "CCAATNNNNNN" sequence into the promoter region of a modified vector (see especially Figure & legends 1 and 2).

Contrary to the applicants assertion, the instant base claim 1, from which the instant claims 8-9 now depend, is drawn to wherein the first and second DNA fragment are inserted so that they are arranged sequentially from the 5'-end side to the 3'-end side of said promoter and that the Region IIIa taught by Minetoki et al represents the instant "second DNA fragment" while the Region IIIb taught by Minetoki et al represents the instant "first DNA fragment". However, Minetoki et al clearly teach wherein the multiple copies of the Region IIIa and IIIb are inserted into the promoter such that, for example, the following DNA fragments are arranged sequentially from the 5'-end side to the 3'-end side of said promoter: Region IIIa, Region IIIb, Region IIIa, Region IIIb, Region IIIa Region IIIb (see p.461, Figure 2). Therefore, the effect of the multiple copies of the Region IIIa and Region IIIb is that Region IIIb (the first DNA fragment) is actually arranged sequentially on both sides of the Region IIIa (the second DNA fragment). In addition, a broad, reasonable interpretation of an "SRE sequence" could read on

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the nucleotide sequence "5'-ATTTAAAG-3'" which is contained in an SRE consensus sequence (see instant application SEQ ID No. 6).

In addition, Minetoki et al teach using the modified promoter in the context of an expression vector (for example, the *agdA* gene is shown in page 463, Figure 5 as the target gene behind the modified promoter in the expression vector construct), and further teach the culturing the host fungus and collecting the produced enzyme protein (e.g. page 461, lines 6-10), which meets the limitations of Claims 15-19.

Therefore, the Minetoki et al reference meets all of the limitations of the instant claims 1, 8-9, and 15-19, as written and Claims 1, 8-9 and 15-19 stand rejected under 35 U.S.C. 102(b) as being anticipated Minetoki et al for reasons of record and above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 11-12, and 15-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Minetoki *et al.*, as applied to claims 1, 8-9 and 15-19 above, and further in view of Boel *et al* (US Patent No. 5,536,661: issued 16 July 1996, of record). The rejection of cancelled Claim 7 is moot.

The applicants arguments (addressed below) have been fully considered but are unpersuasive.

Initially, it is noted that the instant claims are directed to a product and not to the process by which the product was made. The MPEP [2113 [R-1]] states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps". The MPEP states that

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claims 1, 8-9 and 15-19 are taught by Minetoki *et al.* for the reasons above.

However, Minetoki *et al.* differs from the invention claimed in the instant Claims 2-3, and 11 in that while it teaches the generic sequences of Claim 1 (i.e. SEQ ID NO:1-2), used as a modified promoter for the *Aspergillus oryzae* taka-amylase gene, Minetoki *et al.* fails to teach the specific species of SEQ ID NO: 3-4 and 9) (instant Claims 2-3, and 11). Minetoki *et al.* also differs in the instant Claim 12 in that although it contemplates using the amyB promoter (also called TAKA-amylase promoter) in future studies, it does not explicitly use the amyB promoter in the study of reference.

Boel *et al.* teach the use of the SEQ ID NO: 3-4 and 9 and explicitly uses the TAKA-amylase (*amyB*) promoter in *Aspergillus oryzae*.

Firstly, Boel *et al.* teach a construction of a vector comprising a "TAKA-amylase promoter or functional parts thereof" for expression of a protein in *Aspergillus* (see especially abstract, lines 10-13). Boel *et al.* further teach wherein the promoter contains a first base sequence "CCAATTAGAAG" and a second base sequence "CGGAAATTTAAAGG" that are arranged sequentially from the 5'-end side to the 3'-end side of said promoter (see especially sequence of Figure 1, lines 17-19 and Boel *et al.* claims 1-3). Boel *et al.* teach the sequence "5'-ATTTAAAG-3'" which is upstream to the said first and second DNA sequences. Furthermore, Boel *et al.* teach the modification of the *Aspergillus oryzae* taka-amylase promoter in the context of a vector expression system explicitly designed for expressing target proteins of interest for commercial protein production.

Therefore, Boel *et al.*, in view of Minetoki *et al.*, render obvious the modified promoter of claim 1, and further wherein said promoter capable of functioning in a filamentous fungus is a promoter of Taka-amylase of *Aspergillus oryzae*, which meets the limitations of claim 12.

Furthermore, Boel et al teach a vector in which the modified promoter is integrated (claim 15) and a structural gene of a targeted protein is integrated under control of the modified promoter (claim 16) and further teaches wherein a transformed filamentous fungus comprises the vector and is capable of expressing said structural gene (claims 17-18), and producing a protein by culturing the filamentous fungus of claim 18 under conditions capable of producing protein; and collecting the produced protein (claim 19). For example, Boel et al recite "the gene for the desired product functionally linked to promoter and terminator sequences may be incorporated in a vector containing the selection marker' or may be placed on a separate vector or plasmid "capable of being integrated into the genome of the host strain" (col. 12, ¶ 1, lines 1-5). In addition, Boel et al teach the Taka-amylase promoter and collection of produced protein by accumulation of expressed protein in cells, followed by cell disruption, or preferably, by collection of expressed proteins after proteins are secreted from host cells (col. 11, ¶ 2, lines 1-6 and abstract, lines 1-17 and Boel et al claim 5).

Therefore, Boel et al in combination with Minetonga et al meets all the limitations of claims 1-3, 11-12, and 15-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the specific promoter sequences and vector system of Boel et al in the method taught in Minetoki *et al.* because Boel et al teach that the specific sequences and vector system was successfully used for expressing target genes in *Aspergillus*, was available, and was routine (e.g. col. 11, ¶ 2, lines 1-6 and abstract, lines 1-17 and Boel et al claim 5).

One would have been motivated at the time the invention was made to have utilized the SEQ ID NO: 3, 4 and 9 of Boel et al in the method of Minetoki because the Minetoki et al study

particularly focuses on the modification and enhancement of the promoter regions of the three amylase-encoding genes *amyB* (also called taka-amylase or TAA), *glaA* and *agdA* of *Aspergillus oryzae*. For example, Minetoki et al show motivation to explicitly use the sequences of the Taka-amylase promoter in the statement: “On the other hand, high-level expression signals, such as the *amyB* and *glaA* promoters, are frequently used for the overexpression of homologous and heterologous genes in a variety of filamentous fungi”. Minetoki et al continue, “If high-level expression of *amyB* and *glaA* is dependent on region III, the insertion of region III into the promoter region could further elevate expression”. Furthermore, Minetoki et al states that “In this study, multiple copies of the fragment comprising region III were introduced into *Pagda* to enhance promoter activity and to determine the common regulatory mechanism for the repression of the *A.oryzae* amylase genes. The effect of introducing this fragment on gene expression is discussed. In addition, the merits of a conventional solid-state culture system of protein production are described”. (e.g. abstract, lines 1-4; p.459, right column, lines 1-4; and p. 460, left column, ¶1-2). In addition, both Minetoki *et al.* and Boel *et al.* are in the same field of endeavor (promoter sequence construction) and both are directed to the same problem sought to be solved (enhanced promoters capable of use in a filamentous fungus).

Absent evidence to the contrary, one would have a reasonable expectation of success combining the teachings of the art because: the use of the SEQ ID NO: 3, 4 and 9 for the purpose of enhanced promoters capable of functioning in a filamentous fungus was successfully practiced by Boel *et al.* and are a species of the consensus sequences used by Minetoki et al (described in the instant claim 1); the use of the vector system of Boel et al was successfully used and was amenable to modifications (insertions, substitutions, deletions) of the promoter

sequence as shown by the variations of promoter constructs reported in Boel et al; and the use of the specific *Aspergillus oryzae* amylase promoter was shown to be successfully used in Boel et al.

Applicants response is to traverse the 103(a) rejection, stating that, as discussed above for the traversal of the rejection under 102b as being anticipated by Minetoki et al, “the Minetoki reference fails to teach all the elements of the invention as instantly claimed”. In particular, Applicants argue that “the Minetoki et al. reference fails to teach a modified promoter where a first DNA fragment and a second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter region”. Furthermore, Applicants argue that “the Boel reference does not cure the defects of the Minetoki reference, stating that “Nowhere in the Boel reference is there teaching or suggestion of a modified promoter with an existing CCAAT sequence and an existing SRE as instantly claimed”. Therefore, Applicants argue that “the teachings of the cited art, when combined, do not result in the claimed invention”.

The applicants arguments have been fully considered but are unpersuasive because The instant claims are directed to a product and not to the process by which the product was made. The MPEP [2113 [R-1]] states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps”. The MPEP states that

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Amended Claim 1 is directed to a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter wherein one first DNA fragment and one second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, and wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter region, and wherein the modified promoter is capable of functioning in a filamentous fungus. In addition, it is noted that the sequence "CGGAAATTTAAAGG" also reads on a full-length SRE sequence (described above) which meets the limitations of the newly amended Claims 1 and 11.

Minetoki et al teach wherein a plurality of said first DNA fragments and a plurality of said second DNA fragments are inserted (claim 8), and further to wherein the same number of said first DNA fragments and said second DNA fragments are inserted (claim 9). For example, Minetoki et al teach modification of the promoter for the *Aspergillus oryzae* amyB gene (see title and abstract). Furthermore, Minetoki et al teach inserting multiple copies of Region IIIa sequence which contains the second base sequence "CGGAAATTTAAAGG" inserted in tandem with the Region IIIb sequence which contains the first DNA fragment including the "CCAATNNNNNN" sequence into the promoter region of a modified vector (see especially Figure & legends 1 and 2).

Contrary to the applicants assertion, the instant base claim 1, from which the instant claims 8-9 now depend, is drawn to wherein the first and second DNA fragment are inserted so that they are arranged sequentially from the 5'-end side to the 3'-end side of said promoter and that the Region IIIa taught by Minetoki et al represents the instant "second DNA fragment" while the Region IIIb taught by Minetoki et al represents the instant "first DNA fragment". However, Minetoki et al clearly teach wherein the multiple copies of the Region IIIa and IIIb are inserted into the promoter such that, for example, the following DNA fragments are arranged sequentially from the 5'-end side to the 3'-end side of said promoter: Region IIIa, Region IIIb, Region IIIa, Region IIIb, Region IIIa Region IIIb (see p.461, Figure 2). Therefore, the effect of the multiple copies of the Region IIIa and Region IIIb is that Region IIIb (the first DNA fragment) is actually arranged sequentially on both sides of the Region IIIa (the second DNA fragment). In addition, a broad, reasonable interpretation of an "SRE sequence" could read on the nucleotide sequence "5'-ATTAAAG-3'" which is contained in an SRE consensus sequence (see instant application SEQ ID No. 6).

In addition, Minetoki et al teach using the modified promoter in the context of an expression vector (for example, the *agdA* gene is shown in page 463, Figure 5 as the target gene behind the modified promoter in the expression vector construct), and further teach the culturing the host fungus and collecting the produced enzyme protein (e.g. page 461, lines 6-10), which meets the limitations of Claims 15-19.

Therefore, the Minetoki et al reference meets all of the limitations of the instant claims 1, 8-9, and 15-19, as written and Claims 1, 8-9 and 15-19 stand rejected under 35 U.S.C. 102(b) as being anticipated Minetoki et al for reasons of record and above and thus, in view of the

foregoing, the method of claims 1-3, 11-12, and 15-19, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims stand rejected under 35 USC §103(a).

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE S. HIBBERT, whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.
/NANCY VOGEL/

Primary Examiner, Art Unit 1636

Respectfully submitted,

Catherine Hibbert
Examiner AU1636